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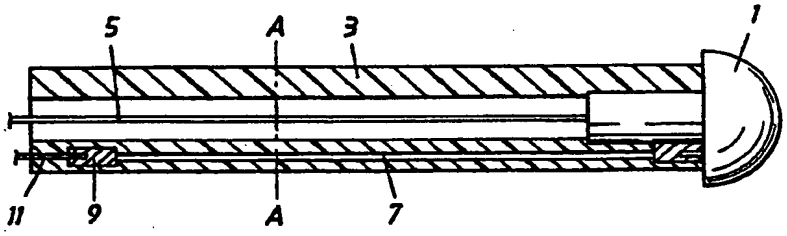

(57) Abstract

A sensor in particular for a heart stimulator is arranged to measure or detect the bending of an electrode lead. A heart stimulator with a lead comprising such a sensor is also claimed. From the bending e.g. contraction movements of the heart muscle can be deducted. The sensor has two parallel channels (7) extending form the tip (1) of the lead inside the wall material of an isolating sleeve (3) enclosing the conductor element (5) of the lead. The channels (7) are filled with an electrically conductive medium. When the lead is subjected to bending movements, the resistance of the medium between the tip electrode (1) and inner connectors (9) will change owing to deformation of the originally straight, cylindrical channels (7). The resistance of the channel medium is sensed by a monitoring device. In addition, the two detector channels (7) are located at asymmetrical places of the lead, whereby also the orientation of the bending movements can be sensed by comparing the bending signals from the channels to each other. This provides more information on the contraction movements so that it can be possible to distinguish between different types of contraction movements, such as normal, stimulated or pathologic.

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A BENDING SENSOR FOR AN IMPLANTABLE LEAD AND A HEART STIMULATOR WITH A LEAD COMPRISING SUCH A SENSOR

TECHNICAL FIELD

The present invention relates to a sensor for detecting movements of muscle or body tissue, in particular a sensor for an implantable heart stimulator, by means of which the contraction of a heart can be measured and/or determined.

BACKGROUND AND STATE OF THE ART

In situations where an implanted stimulator is used, it is normally important to detect the muscular contraction of the stimulated muscle. For example, in the case of a pacemaker the heart contraction is of special interest. Heart contractions may generally have different origins and hence differ significantly from each other as to their characteristic shape or dependence of time. They may be normal, thus triggered by the internal conduction or "nervous" or purkinje system of the heart, stimulated or of type extra contraction (extra systole; VES, SVES or PVC). In sensing heart contractions by means of electrical measurements stimulation polarization potentials and muscular movement interference can create noise virtually making the measurements impossible. In these cases, a device sensitive to the mechanical contraction of the contraction of the stimulated, would confirm and improve the function of a heart stimulator.

In some situations it would be of interest to know also the efficiency of the stimulation or the direction of the stimulation propagation in order to improve the stimulation device or method, such as improving the stimulation algorithm. Examples of such cases are where a differentiation is wanted or required between conducted (normal) contraction and stimulated contraction of the heart (Autocapture), where a differentiation is wanted between normal conducted contraction and extra systole and where ischemia is to be detected. In those cases the change of contraction propagation in the heart muscle will be different, since the propagation pattern or the direction of the contraction movement will be different. For example, in cardiac ischemia,

a portion of the heart wall or heart muscle suffers from an insufficient oxygen supply. This means that a propagating depolarization and thus the contraction cannot pass this portion or at least is subject to a delayed conduction and thus contraction. As a result, alternative propagation paths are favoured, causing a change in the movement pattern. In order to detect such types of pathological changes so that they can be taken into account when stimulating or monitoring the heart function, a device is needed which is capable of sensing differences in the movement pattern.

Prior methods of sensing heart contraction comprise:

- Intracardiac Electrographic Monitoring (IEGM), which does not always however reflect the actual contraction activity as already indicated above, owing to the electrical measurement made. The measurement can thus be disturbed by other electrical signals such as from muscular activity and polarization. Direction, changes of movement pattern or generally the character of the contraction cannot be determined. The measurement only informs on the changes that occur in a close vicinity of the site of the sensing electrode.
- Systolic pressure sensing gives information on the contraction and possibly also the efficiency thereof. It might not be too much affected by other body movements and is not affected by electrical signals. However, it cannot detect the propagation direction or changes in the movement pattern.
- Measuring by means of an accelerometer. However, this method senses only contraction forces and does not sense the propagation direction or changes in the movement pattern.
- Measuring using ultrasonic waves. However, no implantable device is available. The current consumption for making the measurements is too high.
- Measuring the impedance of the heart. This could be done for example between an electrode and the pacemaker housing. However, it can sense only changes of the heart volume.

In U.S. patent 5,514,171 a pressure and heart movement sensor of the systolic pressure sensing type is disclosed. An electric quantity is measured between two electrical conductors in the electrode cable. In one embodiment, see Fig. 2, a sensor medium such as an electrolyte is enclosed in an elongated cavity having elastic walls. The cavity is formed by a widened portion of an elastic tube, which in its other portions is collapsed only enclosing centrally an electrical conductor. The impedance is measured between two conductive plates located at each end of the cavity, the impedance varying in dependence of the pressure of the ambient medium where the sensor cavity is placed. It is not described how this sensor cavity and associated conductors can be incorporated in an electrode lead for a heart stimulator. Other systolic pressure sensors are disclosed in U.S. patents 4,784,151, 4,924,872 and 4,600,017.

SUMMARY OF THE INVENTION

It is an object of the invention to provide a sensing device that can be incorporated in an electrode lead for an implantable stimulator and is capable of detecting movements of the surrounding tissue where it is placed, in particular movements of the heart muscle.

It is another object of the invention to provide a sensing device for sensing tissue movements that is not affected by the environment or any electrical phenomena in the tissue.

It is another object of the invention to provide a sensing device that is capable of sensing the orientation of movements of the surrounding, where the sensing device is placed, in particular the orientation of a contraction caused by a depolarization propagating in a muscle such as the heart muscle.

The problem that is solved by the invention is thus to provide a sensor that can be built into for example an electrode lead for a heart stimulator, that is substantially

unaffected by electrical signals from muscle activity and signals originating from stimulation and that can detect movements of body tissue, in particular the orientation of movements and changes of movement patterns.

Thus, a sensor that is particularly adapted to be incorporated in a heart stimulator comprises means for measuring or detecting the bending of an elongated body in which the measuring means are placed, the body preferably being an electrode lead which is part of an implantable system adapted for muscular or neuron stimulation in a living being, in particular a heart stimulator, the body thus e.g. being an electrode lead included in the electrode system of a heart stimulator. In practice, the tip end of such an electrode lead is positioned in contact with the muscle to be stimulated, i.e. in the preferred case with the heart. The end portion of the lead is placed to have an arched or curved configuration so that the tip end will maintain its contact with the tissue in order to coop with growth, movements and stretching of the living being in which the electrode lead is arranged. When the muscle contracts and thus is getting thicker, the bending radius of the lead end portion will be lower and thus the curvature thereof larger.

The bending measurement means used can be any prior type capable of providing some electrical signal responding to a bending movement of the measurement means and of the material to which the means are attached. For example, it is possible to use a device containing an electrically conducting material that is arranged so that it changes its electrical characteristics when it is subjected to bending. One type of devices contain resistance elements that change their resistance when deformed, such as strain gauges. The resistance element is then attached to some suitable flexible body that follows the movement of the medium or tissue where it is placed.

By attaching two such detector elements in one electrode lead at asymmetrical positions in the lead, in addition the orientation of the bending movement can be sensed. Since a lead normally is elongated and/or cylindrical, the term asymmetrical for the case of two detector element means that the detector elements are not placed at diametrically opposed locations, i.e. not in the same plane extending through the longitudinal axis of the body. Preferably, they are instead located in planes through the longitudinal axis, which form an angle of 30° - 150° to each other, the angle preferably being essentially equal to 90°. The detector elements should also be located at or in the same longitudinal region of the lead in order to provide information on the bending movement. Such an arrangement of two mechanical detector elements can thus be generally used in order to obtain valuable information on bending directions. In the case where more than two detector elements are used, at least one pair of detector elements should have the asymmetrical position as described above.

A resistor element used in the sensing means comprises preferably a channel in the lead body, extending in the longitudinal direction thereof. The body can be an electrically isolating sleeve surrounding a central electrical conductor and then the channel is located in the material of the sleeve, the sleeve having the same uniform inner and outer diameter also at the region where the channel is made. The channel is filled with an electrically conductive fluid, such as a suitable electrolyte, e.g. a salt diluted in water, preferably a saline solution being biologically inert to body fluid. Measurement means are electrically connected to the ends of the channel for measuring the resistance of the fluid between the ends of the channel. The fluid is thus located in a closed cavity. When the lead is subjected to a bending movement, the cavity changes its shape, in particular its diameter, and then also the resistance of the enclosed fluid changes. Such a device could generally also be sensitive to the ambient pressure,

see U.S. patent 5,514,171 discussed above, but by using a substantially incompressible fluid, i.e. a fluid which does not change its volume significantly when subjected to the pressures existing at the place where the sensor is intended to be used, a change of the ambient pressure will not influence the resistance of the enclosed amount of fluid.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described in detail by way of a non-limiting embodiment with reference to the accompanying drawings in which:

- Fig. 1 is a schematic illustration of a heart stimulator with an electrode lead inserted into a heart,
- Fig. 2 is a cross-sectional view of an electrode lead for a heart stimulator comprising a sensor located close to the tip of the electrode lead, the section being taken in the longitudinal direction of the electrode lead,
- Fig. 3 is a cross-sectional view of the electrode lead of Fig. 1, the section being taken perpendicularly to the longitudinal direction of the electrode lead along line A-A, and
- Fig. 4 is a block diagram showing an equivalent electrical circuit of the sensor according to the invention.

PREFERRED EMBODIMENT

In Fig. 1 a heart stimulator 10 with an electrode lead 11 comprising a tip electrode 1 is shown. The proximal end of the electrode lead is attached to the heart stimulator 10 and the distal part of the electrode lead is inserted into a heart 12.

In Fig. 2 the end portion of an electrode lead or cable for a heart stimulator according to a preferred embodiment of the invention is shown. It has a tip electrode 1 at the end of the lead, the tip being made of an inert, electrically conducting material. The tip 1 is attached to a flexible lead sleeve 3 made of a flexible, electrically insulating material such a suitable polymer, normally silicon. The outer diameter of the electrode lead is in the range of 1-3 mm, preferably 2

mm. Inside the sleeve 3 extends centrally an electrically conducting wire 5, e.g. a helical wound, which is attached to the tip electrode 1 for providing an electrical heart stimulation pulse thereto. The insulating sleeve 3 has a rather thick wall, preferably less than 1 mm.

In the wall of the sleeve 3 at least two parallel channels 7 extend from the tip 1 and have a length of a few centimetres. Each of the channels 7 ends at a channel connector 9, located in the wall of the sleeve 3. From each channel connector extends an electrically conducting wire 11 embedded in the wall of sleeve and electrically isolated from the other conducting wire and the tip conductor 5, up to a monitoring device 13 (in Fig. 4) in e.g. a heart stimulator. The channels 7 have a generally straight configuration. As is seen in the transversal cross-section of Fig. 3, in the preferred case of two channels 7, they are located asymmetrically and advantageously at an angular interval from each other, that is substantially 90□, as taken in regard of the longitudinal axis of the electrode lead.
According to an alternative embodiment of the invention the channels can be placed anywhere along an electrode lead and thereby enabling measurements at any site along the lead.

The channels 7 are filled with an incompressible, electrically conducting fluid, e.g. an electrolyte such as a saline solution comprising 0.9% NaCl which is compatible and isotonic with the fluids of the human body. An electrical current can be conducted from the monitoring device 13 through the tip conductor 5, the tip 1, the conducting fluid in one of the channels 7, the respective connector device 9 and conductor 11 back to the monitoring device. The electrical resistance of this conductive path is measured and evaluated. When the end portion of the electrode lead is bent, the diameters of the channels change and they can be widened or narrowed depending on the orientation of the bending. If the conductive fluid is assumed to be incompressible, the volume of the channels will be constant

and then at the inner side of the bending, at its concave side, a channel located there will have its cross-sectioned widened, and at the outer side of the bending, at the convex side of the bending, a channel located there will have its cross-section narrowed. The isolating sleeve is supposed to be rather rigid so that is not sensitive to pressure changes in the medium surrounding the electrode lead.

The resistance of the electrically conductive fluid in a channel 7 between the tip electrode 1 and its connector device will thus change for a bending of the lead and the change will also depend on the orientation of the bending. The monitoring device 13 measures the resistance changes and can therefrom calculate the amount of bending i.e. produce some measure of the bending angle. Further, by comparing the changes of resistance of the loops comprising the two channels 7 to each other it can determine the bending orientation.

In Fig. 4 a block diagram shows an equivalent electrical circuit of the sensor according to the invention. The monitoring device 13, preferably placed in a heart stimulator, is connected to the two channels 7, having a resistance R_1, R_2, respectively. A measurement current I is applied to the channels 7 via the electrical tip conductor 5. According to Ohm's law the relationship then equals I/I_1-1 where I_1 is the current through R_1. The monitoring device measures I_1 and R_1/R_2 is thus easily determined and used to determine the amount of bending and the bending orientation as indicated above.

The applied measurement current I is chosen to a value well below the current used for stimulation, which in pacemakers of today is in the order of 1-10 mA. A preferred range for the measurement current is 1-10 μA, preferably 2-6 μA, and the current can be applied both as AC and DC.

The bending measurement can be performed during the whole heart cycle or only during a specific time window that is started after an intrinsic heart event or an applied heart stimulation pulse (in the atrium or in the ventricle). The

length of the time window can be optionally chosen. If bending should be measured related both to the depolarisation and repolarisation of the heart tissue, the time window is chosen to approximately 300 ms or if bending related only to depolarisation should be measured a time window that is only about 100 ms is required.

CLAIMS

1. A sensor for detecting movements of living tissue, comprising a lead containing at least one electrical conductor, **characterized by** bending measurement means in the lead for measuring the amount and the orientation of the bending of said lead.

2. A sensor according to claim 1, **characterized in** that the lead is an electrode lead being part of an implantable system adapted for muscular or neuron stimulation in a body, in particular a heart stimulator.

3. A sensor according to one of claims 1 - 2, **characterized in** that the bending measurement means comprises at least two separate sensing means (7) located at or in the same longitudinal region of the lead and further located asymmetrically in relation to a longitudinal axis of the lead.

4. A sensor according to claim 3, **characterized in** that two of the separate sensing means (7) are located angularly offset from each other in relation to the longitudinal axis, the offset angle being in particular comprised within 30° - 150° and preferably substantially equal to 90°.

5. A sensor according to one of claims 1 - 4, **characterized in** that the bending measurement means (7) comprise a channel in the lead, the channel being filled with an electrically conductive fluid, and resistance measurement means (13) electrically connected to the ends of the channel for measuring the resistance of the fluid.

6. A sensor according to claim 5, **characterized in** that the bending measurement means comprise two parallel channels in the lead.

7. A sensor for detecting movements of living tissue, comprising a lead containing at least one electrical

conductor and a sensor element for detecting a mechanical quantity at a localized region of the medium or tissue surrounding the lead, **characterized by** at least two identical such sensor elements (7) arranged for detecting the mechanical quantity at or in the same plane perpendicular to a longitudinal axis of the lead and further arranged to detect the mechanical quantity in regions located asymmetrically in relation to the longitudinal axis of the lead.

8. A sensor for detecting movements of living tissue, comprising a lead comprising an electrically isolating sleeve (3) enclosing at least one electrical conductor, **characterized by** at least two channels (7) extending in the material of the sleeve, the channels being filled with an electrically conductive fluid, and measurement means electrically connected to the ends of the channels for measuring the resistance of the fluid.

9. An implantable heart stimulator comprising an electrode lead, **characterized by** a sensor according to one of claims 1 - 8, the lead of the sensor being the electrode lead.

10. An implantable heart stimulator according to claim 9, **characterized in** that the sensor is located at a tip of the electrode lead.

11. An implantable heart stimulator according to claim 9 when depending on one of claims 5, 6 and 8, **characterized in** that the channels (7) respectively extend from an electrically conducting tip of the electrode lead, the tip being one electrical connector of the fluid enclosed in the channels.

Fig. 1

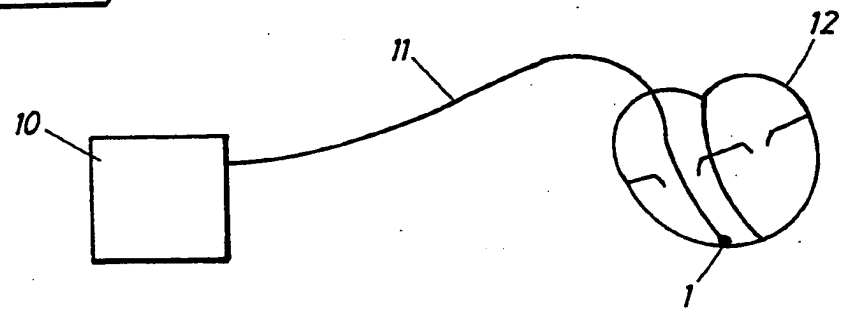
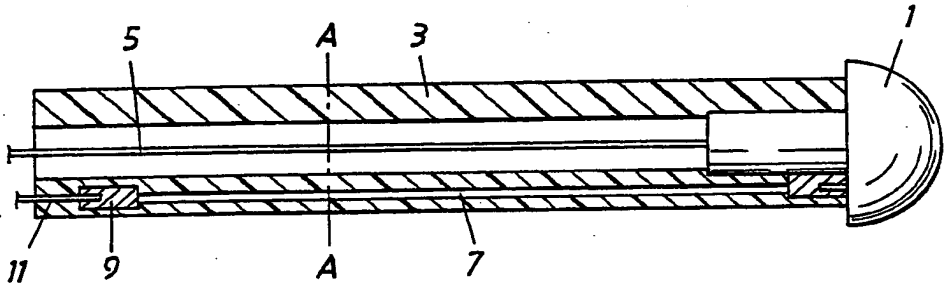


Fig. 2



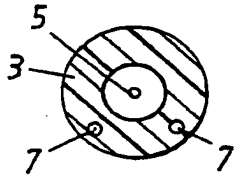
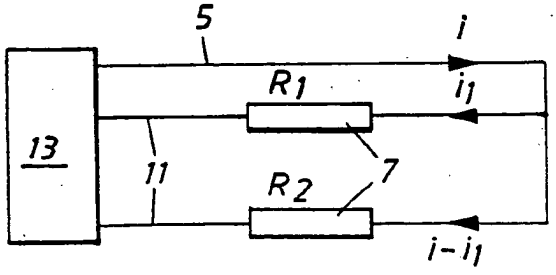


Fig. 3

Fig. 4



INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 98/02128

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61N 1/05, A61B 5/02, A61N 1/362
According to International Patent Classification (IPC) or to both national classification and IPC

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4600017 A (E.A. SCHROEPPEL), 15 July 1986 (15.07.86), column 2, line 7 - line 14; column 3, line 17 - column 4, line 7, cited in the application --	1-2
X	US 5514171 A (K. HOEGNELID ET AL), 7 May 1996 (07.05.96), column 1, line 65 - column 2, line 43, abstract, cited in the application --	1-2
A	US 5109842 A (D.W. ADINOLFI), 5 May 1992 (05.05.92), figure 11, abstract -- --------	1-11

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		US 4802481 A	07/02/89
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